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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Tsutomu Okada

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EXAMINER

HUPCZEY, JR, RONALD JAMES

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/823,814	<b>Applicant(s)</b> OKADA, TSUTOMU	
	<b>Examiner</b> RONALD J. HUPCZEY, JR.	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 7-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 7-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 17<sup>th</sup>, 2009 has been entered.
2. Applicant's amendments and arguments, received on February 17<sup>th</sup>, 2009, have been fully considered by the examiner. Currently, claims 1 and 7-10 are pending with claim 1 currently amended. The following is a complete response to the February 17<sup>th</sup>, 2009 communication.

### ***Claim Rejections - 35 USC § 103***

3. Claims 1 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kokai (Pub. No. 4-329944) in view of Rexroth et al (hereinafter "Rexroth")(US Pat. No. 4,943,290).

Regarding claim 1, Kokai discloses a radio knife (electrosurgical device **1**) containing an electrically insulating sheath (insulating flexible tube **2**) having one flow channel inside (see channel in Figure 1), a distal end portion and a proximal end portion, the distal end portion of the sheath having a distal opening (tip opening **13**) and an axis, a support member (stopper member **4**) which closes the distal opening of the sheath (see Figure 4), the support member having a slide hole with a diameter smaller than that of the distal opening extending along the axis thereof (see Figures 1 and 4); an operating wire (operation wire **14**) axially moveable in the sheath (see paragraph [0013], lines 4-6), the rod-shaped portion being passed through the slide hole for axial

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projection and retraction (movement represented by **X**, see Figure 5); a control section (operation part **3**, operation handle **15**) which is provided on the proximal end portion of the sheath (see Figure 5) and controls the operating wire to project and retract the electrode portion in the axial direction (see paragraph [0013], lines 8-14), the control section having a high-frequency current supply portion (see paragraph [0010], lines 6-8) which supplies high-frequency current to the electrode portion (see paragraph [0011], lines 9-12), a liquid feed portion (cock **17**) which is provided on the proximal end side of the sheath and feeds liquid through the one flow channel inside the sheath towards the distal opening (see paragraph [0014]) and an opening for liquid feed which is formed in the support member, the opening being arranged around the slide hole (see paragraph [0014], line 3-5), communicating to the one flow channel (see Figure 1 and paragraph [0014]) and partially blocking flow in the vicinity of the distal end portion (see Figure 1). Kokai fails to disclose the inclusion of a plurality of openings arranged around and independently of the slide hole such that the cross sectional area of the plurality of openings is smaller than a cross section area of the only one flow channel and is silent in regard to the conductivity properties of the support member.

Rexroth discloses an electrosurgical device (electrosurgical apparatus **10**) containing an electrically insulating sheath (duct means **70**, see col. 9; 3-5) having a distal end portion and proximal end portion, the distal end portion of the sheath having a distal opening and an axis (see Figure 4). Rexroth further discloses the insulation sheath to inherently form a support member which closes the distal opening of the sheath and is insulating. The insulating tip defines a slide hole for the rod-shaped electrode shaft (electrode shaft **50**), the slide hole having a diameter smaller than that of the distal opening (see Figure 14). Additionally, Rexroth discloses the device

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to have a liquid feed portion (input fluid port **18**) and a plurality of openings (see openings, Figure 6) for liquid feed (see col. 8; 62 – col. 9; 8) arranged around and independently of the slide hole (see Figure 6) providing a superior flow pattern to the proximity of the electrode tip. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a plurality of openings such as those disclosed by Rexroth in conjunction with the device disclosed by Kokai to provide an electrosurgical device with a plurality of openings arranged around and independently of the slide hole. As disclosed by Rexroth, it is old and well known to provide a plurality of openings for liquid to flow from in order to create a superior flow pattern to the proximity of the electrode tip. The addition of the plurality of holes in fluidic communication with the only one flow channel would, due in part to the added material required to form the plurality of holes, render the cross section area of the plurality of holes to be less than that of the only one flow channel. Furthermore, it would have been obvious to provide for an electrically insulative support member as disclosed by Rexroth to the device of Kokai to prevent the short circuiting of the device.

Regarding claim 7, Kokai discloses the sheath to have an extending portion extending ahead of the support member wherein the extending portion has an internal space which stores the electrode portion (see Figure 5).

Regarding claim 8, Kokai fails to disclose an extending portion location on the distal end portion of the rod-shaped portion and extending across the extending direction of the rod-shaped portion and for the extending portion to be a hooked bent portion extending substantially at right angles to the distal end portion. Rexroth discloses the electrode portion (electrode shaft **50**) to contain an extending portion (ball tip **26**) located on the distal end portion of the rod-shaped

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portion and extending across the extending direction of the rod-shaped portion (see Figure 15).

Rexroth further discloses the extending portion to be a hooked bent portion (electrode tip **26C**) extending at substantially right angles to the distal end portion (see Figure 18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Kokai with the electrode tip designs disclosed by Rexroth in order to catch tissue around the extending portion.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kokai (Pub. No. 4-329944) in view of Rexroth et al (US Pat. No. 4,943,290) as applied to claim 8 above, and further in view of Kittur et al (US Pat. No. 5,846,241).

Both Kokai and Rexroth fail to disclose the inclusion of a plate-like electrode at the distal end portion. Kittur et al discloses a radio knife (electrocautery device **10**) containing an extending portion (moveable head **22**) in a plate-like arrangement (second electrode **24**) coupled to the distal end of the rod-shaped portion (second wire **20**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a plate-like electrode as disclosed by Kittur et al to the joint device of Kokai and Rexroth. All three device disclosed are directed toward the same field of endeavor and the utilization of a plate-like electrode would increase the versatility of the device, effectively allowing it to successfully perform a wider variety of treatments.

#### ***Response to Arguments***

5. Applicant's arguments filed February 17th, 2009 have been fully considered but they are not persuasive.

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In response to applicant's argument that there is no suggestion to combine the Kokai and Rexroth references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the instant case, while Kokai may not contemplate the concept of a liquid supply via an opening which is independent of a slide hole, the exemplary teaching of Rexroth of a plurality of fluid openings and their delivery of a superior flow pattern is relied upon to teach such a limitation and to provide motivation for the combination.

In response to applicant's argument that in Rexroth, the sheath is continuously supported by the support wall from the proximal to distal end, it is noted by the examiner that the teaching of Rexroth, as described above in the rejection of claim 1, is being relied upon to teach the providing of a plurality of openings formed in the support member and for the support member to be electrically insulating. Nowhere in the rejection is it mentioned that the complete support structure of Rexroth is being incorporated into the device of Kokai. Rexroth is being relied upon for its teaching of the plurality of openings and the material properties of the support member

In response to applicant's argument that the provision of the plurality of openings providing a "superior flow pattern" as disclosed by Rexroth does not achieve the advantages of the device of claim 1, the examiner respectfully disagrees. The combined device described in the rejection of claim 1 above provides for each of the claim limitations presented. The forming of a plurality of holes such as that of Rexroth in the support member of Kokai would result in the

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combined cross sectional area for the plurality of holes being less than the cross sectional area of the only one flow channel. Additionally, while applicant is arguing the difference between the fluid flow from the distal end of the device of Rexroth and the instant device as well as the desire to reduce turbulent flow or the formation of eddy currents, the examiner notes that no such criticality appears in the specification. While there are numerous disclosures of the fluid being ejected from the plurality of openings (see at least page 13; 24-27, page 17; 3-5 and page 18; 15-20), there is no such recitation which shows the requirement of a laminar flow or at least the reduction of turbulence/eddy currents. As such, it is the examiner's position that both the combined device of above rejected claim 1 and the instant device would function to eject fluid from the plurality of openings.

In response to applicant's argument regarding the equation of the continuity of fluid and the pressure required to create the desired jet speed of the instant invention, it is noted that as mentioned above, the specification is only requiring the ejecting of fluid from the plurality of openings in response to a pressure supplied by a fluid source and as such, it is the examiner's position that both the combined device of above rejected claim 1 and the instant device would function to eject fluid from the plurality of openings. Additionally, while applicant is arguing that the examiner's interpretation of a "superior flow pattern" is different than the flow pattern created by the instant invention in claim 1, again, applicant's specification only discloses the ejecting of the fluid from the plurality of holes and gives no indication of any critical flow pattern which is required to be created.



***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure; Coen et al (US 2002/0198520 A1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD J. HUPCZEY, JR. whose telephone number is (571)270-5534. The examiner can normally be reached on Mon. - Fri. from 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RONALD J HUPCZEY, JR./  
Examiner, Art Unit 3739

/Michael Peffley/  
Primary Examiner, Art Unit 3739

RJH